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Award Number: DAMD17-03-1-0676

TITLE: Increasing Adherence to Follow-up of Breast Abnormalities in Low-Income Korean American Women: A Randomized Controlled Trial

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REPORT DATE: Sep 2007

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
             Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)* 30-09-2007	2. REPORT TYPE Annual	3. DATES COVERED *(From - To)* 1 Sep 2006-31 Aug 2007

4. TITLE AND SUBTITLE

Increasing Adherence to Follow-up of Breast Abnormalities in Low-Income Korean American Women: A Randomized Controlled Trial

5a. CONTRACT NUMBER

5b. GRANT NUMBER
DAMD17-03-1-0676

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of California
Los Angeles, CA 90095-6900

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Purpose and Scope: The purpose of this study is to design and test an intervention to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDP) and who have missed their first follow-up appointment (at-risk women). The intervention takes place in the form of peer navigation which includes reminder phone calls or home visits by a trained peer counselor to explain the importance of follow-up procedures, emotional support, help with transportation to follow-up appointments, translations, organizing care for children or grandchildren during medical appointments, and other assistance to overcome barriers to follow-up identified during the initial phase of the study.

Major Findings: We have thus far recruited about 120 subjects into our randomized trial. We have conducted 6 month follow-up interviews with 47 women in the control arm and 44 women in the intervention arm. Preliminary analyses based on telephone surveys suggest that 95% of women in the intervention arm and 72% of women in the control arm complete diagnostic follow-up procedures. We will have to assess if chart reviews confirm these self-report findings.

15. SUBJECT TERMS
Adherence to follow-up of breast abnormalities; low-income Korean Women; randomized controlled trial; peer counseling intervention.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	UU	16	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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INTRODUCTION:

The purpose of this study is to design and test an intervention to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDP) and who have missed their first follow-up appointment (at-risk women). The intervention takes place in the form of peer navigation which includes reminder phone calls or home visits by a trained peer counselor to explain the importance of follow-up procedures, emotional support, help with transportation to follow-up appointments, translations, organizing care for children or grandchildren during medical appointments, and other assistance to overcome barriers to follow-up identified during the initial phase of the study.

As reported previously, phase I of the study informed us that a peer navigator intervention may greatly facilitate adherence to follow-up of breast abnormalities by Korean American at-risk women. We have therefore designed an intervention that utilizes a peer navigator model. We are currently conducting a randomized controlled trial to assess the effectiveness of our intervention. We have thus far recruited 120 subjects into our protocol. We have also collected extensive process measures including number and type of intervention activities requested and delivered in order to estimate the feasibility for institutionalizing intervention activities.

BODY:

Following activities as listed in the Statement of Work have been completed:

Task 1: Setup and Formative Research

All of the task 1 components have been completed and have been addressed in our previous reports.

Task 2: Enrolling Subjects into Randomized Trial

a. **Identify eligible subjects (N=253 during the 2 year recruitment), randomize into the study and administer verbal informed consent to intervention subjects (choice of English or Korean).**

Since August 2005, based on the BCEDP clinic logs at the two clinics, we have identified 181 eligible subjects. We were successful in randomizing 120 of them into our study. Seventy three of the enrolled subjects were assigned to the intervention condition and 47 were assigned to the control condition. The smaller number of subjects in the control condition is due to the fact that control subjects are contacted retroactively, which leads to a 6 months delay as compared to the intervention subjects who are contacted prospectively.

Task 3: Conducting Intervention

a.   **Conduct telephone needs assessment and counseling for each newly enrolled intervention subject (N=86). Contact each intervention subject at least once every other week until completion of diagnostic follow-up/treatment. Offer intervention components as appropriate.**

Each woman in the intervention arm has been contacted through telephone or in-person by our peer navigator for needs assessment using our Initial Assessment and Intervention Survey Questionnaire. Once the initial assessment has been made, our peer navigator follows up with each patient to address their identified need (i.e. reminder call prior to appointment, provide transportation, provide translation, fill out paper work at the hospital, provide emotional support, answer questions, etc.). Thus far, 73 women have undergone Initial Assessment and have received the peer navigator intervention.

b.   **Document all contacts, responses to needs assessment questions, intervention requests and activities.**

We are successful in contacting the majority of our subjects through telephone. Initial contacts are made through telephone using the numbers given to us by the participating clinics. Clinics give us one or more telephone numbers and an address for each woman. If we are not successful with the telephone numbers (i.e. disconnected or no longer residing at such location), we contact the clinic for accuracy of numbers and obtain any other alternate numbers. In order to keep track of how much time and how much effort are given to each woman, we are logging all of these activities.

Thus far, 73 women have received assistance from the peer navigator. They have received help in the following ways:
- Providing with transportation (3)
- Rescheduling appointments (43)
- In-person help at the hospital (49)
    - Help with translation (48)
    - Help with filling out the forms (47)
- Providing reassurance (53)
- Answering questions (62)
- Giving reminder calls (56)
- Providing directions to the hospital (33)

c.   **Conduct alternative protocol for intervention subjects who cannot be reached by telephone.**

We have just received approval from the UCLA IRB to send a mail questionnaire to women that we cannot reach by phone. This may help in increasing the response rate.

d.   **After completion of the follow-up survey, provide intervention to women in the control group who did not complete follow-up procedures.**

Many of the women in the control condition eventually complete their follow-up of abnormalities. We are keeping track of how long it took for them to complete their follow-up to assess whether our intervention could shorten this length of time. For those that did not complete their follow-up, we will offer the identical intervention after we complete the 6 month follow-up survey questionnaire. Of the 47 women in the control arm who have completed the six month follow-up survey to date, 34 have completed their follow-up of abnormalities based on self-report. We offered help to the 13 women in the control arm who did not complete follow-up. Only two women agreed to receive help and completed their follow-up with the help of the peer navigator.

Task 4: Collecting Data

a. Collect and compile log sheets from contacts with intervention subjects (process measures) into a data base
Information from the log sheets is being entered into a data base. This task is ongoing.

Components b-c have been completed and have been addressed in our previous report.

d.   Conduct post-intervention survey with all subjects (N=160) 6 months after referral for diagnostic follow-up. Administer verbal consent prior to conducting survey to subjects in the control group.
We are currently conducting post-intervention survey with subjects in both intervention and control arms. Thus far, we have completed 91 interviews (34 control, 42 intervention).

e.   Conduct chart reviews for all subjects (N=160) 6 months after referral for diagnostic follow-up.

This task has not been started.

Task 5: Data Management and Analysis

Components a -d have been addressed in our previous reports. All tasks are completed, except data entry, which is ongoing.

e.   Set up data entry program and enter information from chart reviews

This task has not been started.

f.   Data management and cleaning
Data management and cleaning is ongoing. Additionally, all written data and information storage devices are kept secure in locked filing cabinet. We are also using log-in and password protected computers in order to ensure confidentiality of study subjects.

g.   Data analysis, preparation of annual reports and manuscripts.

At this time, we have conducted preliminary data analyses to prepare the annual reports required by the DOD and for a recent presentation (see attached).

KEY RESEARCH ACCOMPLISHMENTS:

Preliminary analyses of the follow-up surveys suggest that our intervention is effective in increasing adherence to follow-up of breast abnormalities in low-income Korean American who are screened through BCEDP. Complete follow-up is reported by 72% of the women in the control group (34/47) and 95% of the women in the intervention group (42/44). This difference is statistically significant (Fisher's exact test, $p<.004$). We will have to assess if chart reviews confirm these self-report findings.

REPORTABLE OUTCOMES:

In addition to an early presentation that introduced the study in 2005, a more recent presentation provided preliminary data.

Maxwell AE, Jo A, Bastani R. Increasing adherence to follow-up of breast abnormalities in low-income Korean American women. Era of Hope Department of Defense Breast Cancer Research Program meeting, Philadelphia, Pennsylvania, June 8-11, 2005.

Jo AM, Maxwell AE, Thai L, Kim MJ, Bastani R. Assisting Korean American women with follow-up of breast abnormalities. 23rd Annual UCLA Multi-Campus Family Medicine Research Forum. Northridge Hospital Medical Center. May 8, 2007.

CONCLUSION:

The peer navigator intervention is well accepted and appreciated by the women and the participating clinics. Completion rates of diagnostic follow-up procedures are higher than we had expected in this group of women who had already missed their first follow-up appointment. The majority of women in the control group report that they completed all follow-up procedures without assistance. However, completion rates are substantially higher in the intervention group. These preliminary results suggest that a peer navigator intervention is efficacious in this population.

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APPENDICES:

1. Revised Statement of Work
2. Preliminary Results from the Follow-up Survey
3. Abstract: Jo AM, Maxwell AE, Thai L, Kim MJ, Bastani R. Assisting Korean American women with follow-up of breast abnormalities. 23rd Annual UCLA Multi-Campus Family Medicine Research Forum. Northridge Hospital Medical Center. May 8, 2007.

Statement of Work (Revised)

Task 1: **Setup and Formative Research (Months 01-06)**

a. Develop discussion guides for semi-structured interviews (English and Korean, using standard translation procedures including back translations)
b. Identify women who received a referral for follow-up procedures in the past 12 months from BCEDP logs. Conduct telephone interviews (N=20) with these women (Angela Jo, Kim Young)
c. Identify 5 health care professionals through participating sites and conduct semi-structured interviews (Maxwell, Jo, Young)
d. Draft intervention components (strategies, scripts, materials) and assessment forms (intervention activity logs, needs assessment questions) - all materials in English and Korean language
e. Hire and train 3 mature, English-Korean bilingual Korean American peer counselors
f. Establish procedures to identify women who missed follow-up appointments on a daily basis
g. Pretest intervention in 6-10 KA women, revise and finalize
h. Establish randomization procedure

Task 2: **Enroll subjects into randomized trial (Months 07-30)**

a. Identify eligible subjects (N=253 during the 2 year recruitment), randomize into the study and administer verbal informed consent to intervention subjects (choice of English or Korean).

Task 3: **Conduct Intervention (Months 07-33)**

a. Conduct telephone needs assessment and counseling for each newly enrolled intervention subject (N=86). Contact each intervention subject at least once every other week until completion of diagnostic follow-up/treatment. Offer intervention components as appropriate.
b. Document all contacts, responses to needs assessment questions, intervention requests and activities.
c. Conduct alternative protocol for intervention subjects who cannot be reached by telephone.
d. After completion of the follow-up survey, provide intervention to women in the control group who did not complete follow-up procedures.

Task 4: **Data Collection (Months 3-40)**

a. Collect and compile log sheets from contacts with intervention subjects (process measures) into a data base (months 7-35)
b. Develop (draft, translate, back translate, pretest, revise) follow-up survey based on the Adherence Model (months 3-12)
c. Hire and train interviewer(s) to conduct follow-up survey (months 12-13)
d. Conduct post-intervention survey with all subjects (N=160) 6 months after referral for diagnostic follow-up. Administer verbal consent prior to conducting survey to subjects in the control group (months 13-40)
e. Conduct chart reviews for all subjects (N=160) 6 months after referral for diagnostic follow-up (months 13-40)

Task 5: **Data Management and Analysis (Months 1-42)**

a.   Transcribe and translate into English audiotapes from semi-structured interviews.
b.   Analyze qualitative and quantitative data from Task 1.
       For qualitative data analysis, summarize transcripts from semi-structured interviews, including key points and notable quotes (in English and Korean language) using standard procedures (Krueger 1994); compare and consolidate summaries prepared independently by two Korean speaking investigators (Drs. Jo and Kim); sort findings by the domains of the Adherence Model.
       For quantitative analysis, tabulate findings from semi-structured interviews, including specific needs expressed, services requested and barriers and concerns voiced about follow-up procedures. Tabulate findings from chart reviews by adherence status.
c.   Set up data entry programs and enter information from intervention log sheets, needs assessments, intervention requests and activities (process measures)
d.   Set up data entry program and enter information from 6 month follow-up survey
e.   Set up data entry program and enter information from chart reviews
f.   Data management and cleaning will be ongoing
g.   Data analysis, preparation of annual reports and manuscripts.

Deliverables

1st Annual Report
a.   Summary of findings from semi-structured interviews and chart reviews
b.   Intervention protocol, including questions for needs assessment, scripts for barrier counseling, fact sheets to answer frequently asked questions, and intervention strategies (English and Korean)
c.   Training curriculum and materials for KA peer counselors (English and Korean)
d.   Process measures: number of women enrolled; frequency with which intervention strategies are requested, offered, and implemented
e.   Preliminary results of ongoing individual needs assessment

2nd Annual Report
f.   Finalized chart review form and follow-up survey (English and Korean)
g.   Updates on process measures and needs assessment

3rd Annual Report
h.   Preliminary results of 6 month follow-up assessments (chart reviews, surveys)
i.   Updates on process measures and needs assessment

Final Report
j.   Final study protocol including all materials developed for training peer counselors and for delivering the individualized intervention (English and Korean)
k.   Final report on process and outcome measures
l.   Summary of findings for distribution to BCEDP sites (English and Korean)

Appendix 2: Preliminary Results from the Follow-Up Survey

Table 1: Demographic characteristics and acculturation

	total sample		control group		intervention group		p-value (Fisher's Exact Test)
Demographics	**xbar**	**s.d.**	**xbar**	**s.d.**	**xbar**	**s.d.**	
Age	53.00	7.64	53.66	7.56	52.31	7.75	.208
Length of stay in U.S. (years)	17.2	9.12	17.4	9.27	17.03	9.07	.4285
	N	**%**	**N**	**%**	**N**	**%**	
Born in Korea	86	100%	44	100%	42	100%	-
Marital Status							
never married	4	5%	2	5%	2	5%	
married	62	72%	29	66%	33	79%	
divorced	11	13%	9	20%	2	5%	
widowed	9	10%	4	9%	5	12%	.177
Annual household income							
< $10,000	21	25%	10	23%	11	26%	
$10,000 to < $20,000	21	25%	14	32%	7	17%	
$20,000 to < $30,000	17	20%	6	14%	12	29%	
$30,000 to < $50,000	12	14%	7	16%	5	12%	
> $50,000	8	9%	4	9%	4	10%	
don't know	1	1%	0	0%	1	2%	
refuse	5	6%	3	7%	2	5%	.432
Level of education							
less than 8th grade	8	9%	6	14%	2	5%	
8th to 11th grade	5	6%	1	2%	4	10%	
high school graduate	31	36%	21	48%	10	24%	
post high school, trade, tech school	1	1%	0	0%	1	2%	
1 - 3 years college	6	7%	2	5%	4	10%	
college graduate	32	37%	13	30%	19	45%	
some graduate work or degree	1	1%	1	2%	0	0%	
refuse	2	2%	0	0%	2	5%	.038
Acculturation							
Language used with friends							
Korean and English	7	8%	5	11%	2	5%	
Mostly Korean	37	43%	19	43%	18	43%	
Only Korean	42	49%	20	45%	22	52%	.552
Reading language							
Only English	1	1%	1	2%	0	0%	
Half Korean, half English	9	10%	5	11%	4	10%	
Mostly Korean	21	24%	8	18%	13	31%	
Only Korean	55	67%	30	68%	25	60%	.419
Television language							
Mostly English	6	7%	4	9%	2	5%	
Half Korean, half English	18	21%	9	20%	9	21%	
Mostly Korean	25	29%	10	23%	15	36%	
Only Korean	37	43%	21	48%	16	38%	.521
Do you consider yourself …							
More Korean	72	84%	35	80%	37	88%	
More American	3	3%	2	5%	1	2%	
Equal blend	11	13%	7	16%	4	10%	.569

Table 2: General health and health insurance status

General Health	total sample		control group		intervention group		p-value (Fisher's Exact Test)
	N	%	N	%	N	%	
How would you rate your overall health?							
Excellent	4	5%	4	9%	0	0%	
Very good	9	10%	6	13%	3	7%	
Good	20	23%	12	27%	8	19%	
Fair	42	48%	19	42%	23	55%	
Poor	12	14%	4	9%	8	19%	0.126
Has doctor ever told you that you have …							
Heart problems	10	12%	4	9%	6	15%	.508
Stroke	0	0%	0	0%	0	0%	-
Hypertension	15	17%	5	11%	10	24%	.158
Diabetes	2	2%	1	2%	1	2%	1.00
Cancer	3	3%	1	2%	2	5%	.608
Other	31	36%	13	29%	18	43%	.188
Family History of Cancer	37	43%	20	45%	17	40%	.669
How comfortable discussing your health care with physician							
very	18	21%	7	16%	11	27%	
somewhat	55	64%	28	62%	27	66%	
not	3	4%	2	4%	1	2%	
don't know	6	7%	4	9%	2	5%	
refuse	4	5%	4	9%	0	0%	0.222
How worried were you about your future health?							
very	16	19%	10	23%	6	14%	
quite	19	22%	9	20%	10	24%	
a little	40	47%	18	41%	22	52%	
not	11	13%	7	16%	4	10%	.556
Health Insurance							
Has health Insurance	15	17%	6	13%	9	21%	.399
Type of health insurance							
Private	5	45%	0	0%	5	83%	
HMO	5	45%	4	80%	1	17%	
Medi-Cal	1	9%	1	20%	0	0%	.026

Table 3: Self-reported adherence to diagnostic follow-up procedures

	total sample		control group		intervention group		p-value (Fisher's Exact Test)
	N	%	N	%	N	%	
Adherent to follow-up exams	76	84%	34	72%	42	95%	
Not-adherent to follow up exams	15	16%	13	28%	2	5%	.004
Testing site (clinic)							
HPMC	56	75%	23	72%	33	79%	
WBC	11	15%	7	22%	4	10%	
Other - U.S. Location	4	5%	1	3%	3	7%	
Korea	2	3%	1	3%	1	2%	
MK Clinic	1	1%	0	0%	1	2%	.527
Test Results							
Fibroadenoma	2	3%	1	3%	1	3%	
Microcalcifications	4	6%	2	6%	2	5%	
Need further test	10	14%	4	13%	6	15%	
Cancer	3	4%	1	3%	2	5%	
Normal	53	74%	24	75%	29	73%	1.00

Table 4: Knowledge and attitudes regarding diagnostic follow-up procedures

	total sample		control group		intervention group		p-value (Fisher's Exact Test)
Know the exam	N	%	N	%	N	%	
yes	74	84%	37	80%	37	88%	
no	13	15%	8	17%	5	12%	
refuse	1	1%	1	2%	0	0%	.556
Able to correctly explain exam							
yes	57	79%	27	77%	30	81%	
no	15	27%	8	23%	7	19%	.775
Understanding of why doctor/nurse recommended exam							
very well	56	64%	25	56%	31	72%	
pretty well	27	31%	16	36%	11	26%	
not well	5	6%	4	9%	1	2%	.182
How important is it to get a follow up exam?							
very	72	81%	37	80%	35	81%	
somewhat	14	16%	8	17%	6	14%	
not	2	2%	1	2%	1	2%	
don't know	1	1%	0	0%	1	2%	.832
How supportive would your family/friends be?							
very	52	60%	25	54%	27	66%	
somewhat	28	32%	17	37%	11	27%	
not	5	6%	3	7%	2	5%	
don't know	1	1%	0	0%	1	2%	
refuse	1	1%	1	2%	0	0%	.588
Need help on decision to get or not get exam	21	24%	11	24%	10	24%	
Can make the decision alone	66	75%	35	76%	31	74%	
Don't know	1	1%	0	0%	1	2%	.897
With regards to getting my exam, I want to do what my friends think I should do.							
agree	19	22%	10	22%	9	21%	
disagree	68	77%	35	76%	33	79%	
don't know	1	1%	1	2%	0	0%	1.000
Getting the follow up exam gives peace of mind							
strongly agree	31	35%	16	35%	15	36%	
agree	52	59%	28	61%	24	57%	
disagree	4	5%	1	2%	3	7%	
strongly disagree	1	1%	1	2%	0	0%	.641
Worried that exam would show cancer							
very	24	28%	12	27%	12	29%	
somewhat	46	53%	23	51%	23	55%	
not	17	20%	10	22%	7	17%	.844
Nervous about getting breast cancer							
very	22	26%	14	31%	8	22%	
somewhat	45	52%	21	47%	24	59%	
not	19	22%	10	22%	9	22%	.411
Worry/nervousness affected decision to get exam							
encouraged to get exam	66	76%	35	78%	31	74%	
avoided the exam	2	2%	2	4%	0	0%	
did not affect	17	20%	7	16%	10	24%	
refuse	2	2%	1	2%	1	2%	.500

Table 5: Aspects rated as very important for quality of life by Korean-American women

Aspect	N	%
Being healthy	75	89%
Satisfactory family relationships	60	71%
Live without stress	54	64%
Leading a religious life	43	51%
Successful family members	39	46%
Absence of financial difficulties	39	46%
Living honorably	28	33%
Good social networks/relationships	28	33%
Success in work	24	29%
Engaging in activities you like	23	27%

Table 6: Barriers to follow-up exams for breast abnormalities among Korean-American women

Barriers	N	%
lack of time	58	67%
language barriers	58	67%
worried to find cancer	57	66%
believe exam is not necessary without symptoms	54	62%
concerned about cost	51	59%
exam is difficult to schedule	45	52%
long waiting times in facility	43	49%
embarrassment	41	47%
exam is inconvenient to take	35	40%
forget appointment	31	36%
exam is painful	24	28%
lack of social support	21	24%

Assisting Korean American women with follow-up of breast abnormalities

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ABSTRACT

Purpose: Incomplete follow-up of potential breast abnormalities may contribute to disparities in breast cancer survival, especially in low-income, non-white populations. We are evaluating a peer navigator intervention to assist Korean American women who have missed their first follow-up appointment (at-risk women).

Methods: Through partnerships with two community clinics in Koreatown that provide free breast cancer screening to low income uninsured women through the Cancer Detection Program, we plan to randomize 160 Korean American at-risk women to an intervention group that receives help from a Korean American peer navigator or to a control group that receives usual care only.

Results: To date, our peer navigator has assisted 63 women in the intervention group by rescheduling appointments (50%), making reminder calls (81%), providing directions to the hospital (30%), translating (57%), filling out forms (55%), answering questions regarding the follow-up process (94%), and providing emotional support (72%). Among women who have completed six months follow-up interviews, 71% in the control group (25/35) and 95% in the intervention group (31/33) have reported completion of all recommended follow-up procedures (p=.03).

Implications: Our findings suggest a clinically important improvement in adherence to recommended follow-up procedures. If chart reviews confirm our preliminary findings in the total sample, this intervention may assist in decreasing breast cancer disparities among Korean American women.
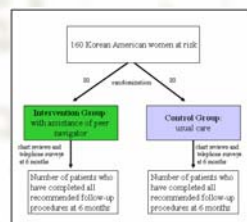
BACKGROUND

- 15-20% of women who receive breast cancer screening require follow-up diagnostics and/or treatment.
- Incomplete follow-up of breast abnormalities ranges from 18 – 80%.
- Factors associated with incomplete and delayed follow-up of breast abnormalities:
  - Older age
  - Low income and education levels
  - Non White race
  - Less social support
  - Concerns about cost, lost wages, transportation
  - Patients' fears
- Barriers that Korean American patients face in completing follow-up:
  - Language barrier
  - Lack of transportation
  - Lack of knowledge of importance of follow-up
  - Fear of getting lost and being helpless at the health care facility
  - Unable to complete paperwork by self
  - Fear of getting reported to the authorities
  - Not understanding that the follow-up is free of charge to them

STUDY AIMS

- Recruit 160 *at-risk* women into the study. Randomize half into usual care and half to intervention condition (individualized peer counselor program)
- Assess adherence to follow-up procedures and related knowledge, attitudes and quality of life via chart reviews and telephone interviews at 6 months.
- Collect process measures in order to estimate the feasibility of institutionalizing intervention activities

METHODS

- A two-arm randomized controlled trial
- Follow-up assessed at 6 months from date of referral through telephone interviews
- Primary outcome variable: **adherence to follow-up procedures (yes/no)**
- Self-report will be validated through chart reviews

PEER NAVIGATOR MODEL

A peer navigator is a trained lay person who may accompany the patient to follow-up appointments and provide emotional support, education, and advocacy.
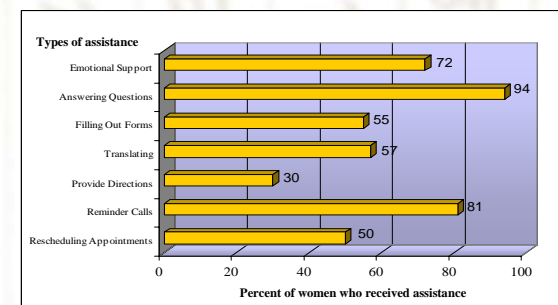
SUGGESTED ROLES OF A PEER NAVIGATOR

- Assist with translation and transportation
- Help with paperwork
- Accompany to doctor visits
- Educate patients on the importance of follow-up
- Educate patients on the details of the CDP program (i.e. free of charge to enrollees, no risk of deportation)
- Answer questions that patients may have
- Provide emotional support
- Advocate in the community for breast cancer

RESULTS

- ❖ To date, our peer navigator has assisted 77 women in the intervention group

Types of assistance

Type of assistance	Percent
Emotional Support	72
Answering Questions	94
Filling Out Forms	55
Translating	57
Provide Directions	30
Reminder Calls	81
Rescheduling Appointments	50

X-axis: Percent of women who received assistance

GROUP*	Compliance Rates to follow-up procedures at 6 months
Control Group	71% (25/35)
Intervention Group	95% (31/33)

p = 0.03
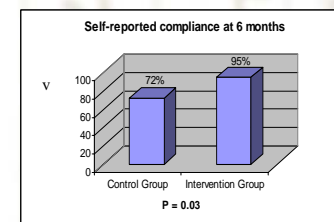
Self-reported compliance at 6 months

	Control Group	Intervention Group
	72%	95%

P = 0.03

IMPLICATIONS

- **Our findings suggest a clinically important improvement in adherence to recommended follow-up procedures.**
- **If chart reviews confirm our preliminary findings in the total sample, this intervention may assist in decreasing breast cancer disparities among Korean American women.**

ACKNOWLEDGEMENT